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Proposed Maximum Residue Limit PMRL2016-71

Penflufen

(publié aussi en français)

7 December 2016

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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ISSN: 1925-0835 (print)
1925-0843 (online)

Catalogue number: H113-24/2016-71E (print version)
H113-24/2016-71E-PDF (PDF version)

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Under the authority of the *Pest Control Products Act*, Health Canada's Pest Management Regulatory Agency (PMRA) has concluded that the addition of new uses on sugar beets to the product labels of EverGol Energy (containing technical grade penflufen, metalaxyl, and prothioconazole) and PEN 240FS (containing technical grade penflufen) are acceptable. The specific uses approved in Canada are detailed on the labels of EverGol Energy and PEN 240FS, *Pest Control Products Act* Registration Numbers 30364 and 30359, respectively.

The evaluation of these penflufen applications indicated that the end-use products have value and the human health and environmental risks associated with the new uses are acceptable.

Before registering a pesticide for food use in Canada, the PMRA must determine the quantity of residues that are likely to remain in or on the food when the pesticide is used according to label directions and that such residues will not be a concern to human health. This quantity is then legally established as a maximum residue limit (MRL). An MRL applies to the identified raw agricultural food commodity as well as to any processed food product that contains it, except where separate MRLs are specified for the raw agricultural commodity and a processed product made from it.

Consultation on the proposed MRL for penflufen is being conducted via this document (see Next Steps, the last section of this document). A summary of the data used to support the proposed MRL can be found in Appendix I.

To comply with Canada's international trade obligations, consultation on the proposed MRL is also being conducted internationally by notifying the World Trade Organization, as coordinated by the Canada's Notification Authority and Enquiry Point.

The proposed MRL, to be added to the MRLs already established for penflufen, is as follows.

Table 1 Proposed Maximum Residue Limit for Penflufen

Common Name	Residue Definition	MRL (ppm)[1]	Food Commodity
Penflufen	*N*-[2-(1,3-dimethylbutyl)phenyl]-5-fluoro-1,3-dimethyl-1*H*-pyrazole-4-carboxamide	0.01	Sugar beet roots

[1] ppm = parts per million

MRLs established in Canada may be found using the Maximum Residue Limit Database on the Maximum Residue Limits for Pesticides webpage. The database allows users to search for established MRLs, regulated under the *Pest Control Products Act*, both for pesticides or for food commodities.

International Situation and Trade Implications

Penflufen is an active ingredient that is concurrently being registered in Canada and the United States for use on sugar beets as a seed treatment. The MRL proposed for penflufen in Canada is the same as the corresponding tolerance to be promulgated in the United States.

Once established, the American tolerances for penflufen will be listed in the Electronic Code of Federal Regulations, 40 CFR Part 180, by pesticide.

Currently, there are no Codex MRLs[1] listed for penflufen in or on any commodity on the Codex Alimentarius Pesticide Residues in Food and Feed website.

Next Steps

The PMRA invites the public to submit written comments on the proposed MRL for penflufen up to 75 days from the date of publication of this document. Please forward your comments to Publications (see the contact information on the cover page of this document). The PMRA will consider all comments received before making a final decision on the proposed MRL. Comments received will be addressed in a separate document linked to this PMRL. The established MRL will be legally in effect as of the date that it is entered into the Maximum Residue Limit Database.

[1] The Codex Alimentarius Commission is an international organization under the auspices of the United Nations that develops international food standards, including MRLs.

Appendix I

Summary of Radio-Labelled Data Used to Support the Proposed Maximum Residue Limit

A radio-labelled study for penflufen in sugar beets was submitted to support the domestic uses of EverGol Energy and PEN 240FS on sugar beets. The data from this study showed no uptake of residues to the aerial portion or root portion of sugar beets grown from treated seeds. Therefore, as per DIR2003-02, no further studies are required.

Maximum Residue Limit

The recommendation for a maximum residue limit (MRL) for penflufen was based upon the submitted radio-labelled study data. Table A1 summarizes the data used to calculate the proposed MRL for sugar beet roots.

Table A1 Summary of Radio-Labelled Data Used to Support MRL

Commodity	Application Method/ Total Application Rate	Days After Planting	Lowest Average Field Trial Residues (ppm)	Highest Average Field Trial Residues (ppm)	Experimental Processing Factor
Sugar beet roots	Seed Treatment/ 2.81 g a.i./100 kg[1]	151	<0.005	<0.005	Not determined

[1] g a.i./100 kg = grams of active ingredient per 100 kilograms

Following the review of all available data, an MRL as proposed in Table 1 is recommended to cover residues of penflufen. Residues of penflufen in this crop commodity at the proposed MRL will not pose an unacceptable risk to any segment of the population, including infants, children, adults and seniors.